OXOJECT - oxytocin injection, solution

Butler

PRODUCT TITLES

OxoJect Oxytocin Injection Purified Oxytocic Principle (20 USP Units per mL)

FOR ANIMAL USE ONLY KEEP OUT OF REACH OF CHILDREN

DESCRIPTION

OXOJect (Oxytocin injection) is a sterile aqueous solution of highly purified oxytocic principle derived by synthesis or obtained from the posterior lobe of the putuitary gland of healthy domestic animals used for food by humans. OXOJect (Oxytocin injection) contains 20 USP Units of oxytocin and less than 0.4 units of presser activity per mL. Each mL of sterile solution also contains 0.9% w/v sodium chloride, 0.5% w/v chlorobutanol (as a preservative), with water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid.

ACTION

Oxytocin acts directly on the smooth musculature of the uterus in all species to induce rythmic contractions, although in some species the uterine cervix does not respond to oxytocin. The responsiveness of the uterine musculature to oxytocin varies greatly with the stage of the reproductive cycle. During the early phases of pregnancy the uterus is relatively insensitive to the effects of oxytocin, while in the late phases the sensitivity is markedly increased. Most authorities attribute this varying response to the varying levels of estrogen and progesterone during the course of pregnancy. Oxytocin also has been shown to exert a milk ejecting effect, occasionally referred to as the galactogogic effect. The actual mechanism by which oxytocin stimulates the release of milk from the mammary glands is not known with certainty, but oxytocin injection is presumed to act on certain smooth muscle elements in the gland.

INDICATIONS

Because of the specific action of oxytocin upon the uterine musculature, it is recommended as an aid in the management of the following conditions:

- 1) To precipitate labor
- 2) To accelerate normal parturition
- 3) Postpartum evacuation of uterine debris
- 4) Postoperative contraction of the uterus following a cesarean section and control of uterine hemorrhage.

Oxytocin will contract the smooth muscle cells of the mammary gland to induce milk let-down if the udder is in a proper physiological state.

CONTRAINDICATIONS

Do not use in dystocia due to abnormal presentation of the fetus until correction is accomplished.

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PRECAUTIONS

Oxytocin is a potent preparation, accordingly, it should be administered with due caution. For prepartum usage full dilation of the cervix should be accomplished either naturally or through the administration of estrogen prior to oxytocin therapy.

DOSAGE AND ADMINISTRATION

Obstetrical Use: Inject aseptically by the intravenous, intramuscular or subcutaneous route as follows:

EWES, SOWS:

1.5 to 2.5mL......30 to 50 USP Units

COWS, HORSES:

5.0mL.....100 USP Units

These dosages are recommended, and may be repeated as indicated.

Milk Let-down:

Inject aseptically by the intravenous, intramuscular or subcutaneous route.

COWS:

0.5 to 1.0mL.....10 to 20 USP Units

SOWS:

0.25 to 1.0mL.....5 to 20 USP Units

These dosages are recommended and may be repeated as necessary.

Note: Oxytocin will not induce milk let-down unless the udder is in the proper physiological state.

CAUTION

CAUTION: Federal law restricts this drug to be used by or on the order of a licensed veterinarian.

HOW SUPPLIED

100 mL multiple dose vials

STORAGE

Store at controlled room temperature.

Do Not Freeze.

PACKAGE LABEL PRINCIPLE DISPLAY PANEL

NDC # 11695-4015-1

Butler Animal Health Supply

OXOJect

Oxytocin Injection

Purified Oxytocic Principle

Sterile Aqueous Solution

FOR ANIMAL USE ONLY

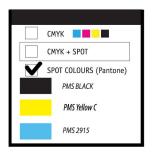
KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

ANADA # 200-328, Approved by FDA $\,$

Net Contents: 100mL (3.4 fl. oz)

Distributed Exclusively by: Butler Animal Health Supply-Dublin, OH 43017



Approved Art September 8, 2009

Butler EACH mL CONTAINS: Oxytocin 20 USP Units, sodium chloride 0.9% w/v, chlorobutanol 0.5% w/v, water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid. ROUTE OF ADMINISTRATION: Intravenous, intramuso **OXOJECT** DOSAGE: For use in inducing rhythmic contractions of the smooth musculature of the uterus and/or milk letdown. For **Oxytocin Injection** Purified Oxytocic Principle complete use directions and precautions see insert. Sterile Aqueous Solution
FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN
CAUTION: Federal law restricts this drug to
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ANADA# 200-328, Approved by FDA Milk Let-down Restricted Drug (California) Use Only as Directed Store at controlled room temperature. Reorder #: 034974 TAKE TIME OBSERVE LABEL DIRECTIONS Trademark of Butler Animal Health Supply, LLC. Manufactured by: Birneda-MTC Animal Health Inc. Cambridge, ON Canada Birneda-MTC Animal Health Inc. is a Division of Cross Vetpharm Group Ltd. System 39 Bar Code Net Contents: 100 mL (3.4 fl. oz) 4034974 Distributed Exclusively by: Butler Animal Health Supply • Dublin, OH 43017 Value Based, Solutions Driven

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administration of estrogen prior to oxytocin therapy.

DOSAGE AND ADMINISTRATION:

Obstetrical Use: Inject aseptically by the intravenous, intramuscular or subcutaneous route as follows: EWES, SOWS:

1.5 to 2.5 mL 30 to 50 USP Units COWS, HORSES:

5.0 mL 100 USP Units These dosages are recommended, and may be repeated as indicated.

Milk Let-down:

Inject aseptically by the intravenous, intramuscular or subcutaneous route. COWS:

0.5 to 1.0 mL10 to 20 USP Units SOWS:

0.25 to 1.0mL5 to 20 USP Units
These dosages are recommended and
may be repeated as necessary.
Note: Oxytocin will not induce milk

let-down unless the udder is in the proper physiological state.

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HOW SUPPLIED:

100 mL multiple dose vials.

Store at controlled room temperature. Do Not Freeze. ANADA# 200-328 Approved by F

Manufactured by: Bimeda-MTC Animal Health In Cambridge, ON Canada

Distributed Exclusively by: Butler Animal Health Supply

OXOJECT™ Oxytocin Injection

Purified Oxytocic Principle (20 USP Units per mL)

FOR ANIMAL USE ONLY HAZARDOUS

KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: OXOJECT™ (Oxytocin injection) is a sterile aqueous solution of highly purified oxytocic principle derived by synthesis or obtained from the

posterior lobe of the pituitary gland of healthy domestic animals used for food by humans. OXOJECT™ (Oxytocin injection) contains 20 USP Units of oxytocin and less than 0.4 units of presser activity per mL. Each mL of sterile solution also contains 0.9% w/v sodium chloride, 0.5% w/v chlorobutanol (as a preservative), with water for injection q.s. and pH adjusted to 3.0 to 5.0 with acetic acid.

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